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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,330	11/03/2003	Herath Mudiyanselage Athula Chandrasiri Herath	2543-1-031	5151

23565 7590 08/17/2006

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EXAMINER	
SANG, HONG	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,330	HERATH ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Herath et al.

Note: Claims 28-29 recite the limitation "administration" in claim 25. Claims 30-31 recite the limitation "in normal control mammals" in claim 25. There is insufficient antecedent basis for these limitations in the claim. Therefore, claims 28-31 are interpreted as being dependent from claim 26.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-2, and 5, drawn to a method for screening or diagnosis of ErbB2 related cancer in a subject, for determining the stage or severity of ErbB2 related cancer in a subject, for identifying a subject at risk of developing ErbB2 related cancer, or for monitoring the effect of therapy administered to a subject having ErbB2 related cancer, comprising analyzing a test sample of body fluid from the subject by 2D electrophoresis to generate a two-dimensional array of features, said array comprising one or more of the EOFs as defined in Table 1, and comparing the abundance of the one or more EOFs in the test sample with that in control sample, classified in class 435, subclass 4.

   If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOF from Table 1 or from claim 2. This election should not be construed as an election of species. This is a

restriction requirement. Each of the EOFs listed in Table 1 or claim 2 is a structurally and functionally distinct molecule (e.g. different PI and MW), which would require a separate search.

II. Claims 3, 4, 6-8, 12-14, and 40-41, drawn to a method for screening or diagnosis of ErbB2 related cancer in a subject, for determining the stage or severity of ErbB2 related cancer in a subject, for identifying a subject at risk of developing ErbB2 related cancer, or for monitoring the effect of therapy administered to a subject having ErbB2 related cancer, comprising quantitatively detecting, in a test sample of body fluid from the subject, one or more of EOPIs as defined in Table III, classified in class 435, subclass 7.1.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3 or from claim 4. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 or claim 4 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

III. Claims 9, 10, and 15-17, drawn in part to a pharmaceutical composition comprising an EOPI protein, a kit comprising one or more EOPIs as defined in claim 3, classified in class 530, subclass 350.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election

should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

IV. Claims 9, drawn in part to a pharmaceutical composition comprising a nucleic acid encoding an EOPI, classified in class 536, subclass 23.1.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

V. Claims 11, and 15-18, drawn in part to an antibody capable of immunospecific binding to an EOPI, a kit comprising one or more antibodies as claimed in claim 11, a pharmaceutical composition comprising a therapeutically effective amount of an antibody according to claim 11, classified in class 530, subclass 387.1.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and

functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

VI. Claims 15-17, drawn in part to a kit comprising one or more antibodies as claimed in claim 11 and one or more EOPIs as defined in claim 3, classified in class 530, subclass 350.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

VII. Claim 19, drawn to a method of treating or preventing ErbB2 related cancer comprising administering an antibody of claim 11, classified in class 424, subclass 178.1.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

VIII. Claim 20, drawn in part to a method of treating or preventing ErbB2 related cancer comprising administering one or more of the EOPI protein as defined in claim 3, classified in class 514, subclass 2.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

IX. Claim 20, drawn in part to a method of treating or preventing ErbB2 related cancer comprising administering a nucleic acid encoding the EOPI protein as defined in claim 3, classified in class 514, subclass 44.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

X. Claims 21-22, drawn in part to a method of treating or preventing ErbB2 related cancer comprising administering a nucleic acid that inhibits the function of one or more of the EOPIs as defined in claim 3, wherein the

nucleic acid is a EOPI antisense nucleic acid, classified in class 514, subclass 44.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XI. Claims 21-22, drawn in part to a method of treating or preventing ErbB2 related cancer comprising administering a nucleic acid that inhibits the function of one or more of the EOPIs as defined in claim 3, wherein the nucleic acid is a EOPI ribozyme, classified in class 514, subclass 44.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XII. Claims 23, 24 and 33-34, drawn to a method of screening for agents that interact with one or more EOPIs as defined in claim 3, comprising contacting an EOPI with a candidate agent, and detecting the binding of the candidate agent and the EOPI, classified in class 435, subclass 7.1.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XIII. Claim 25, drawn in part to method of screening for or identifying agents that modulates the expression or activity of more or more EOPIs as defined in claim 3, comprising contacting a population of cells expressing EOPI with a candidate agent and a control agent, and comparing the level of EOPI protein in the first and second populations of cells, classified in class 435, subclass 7.32.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XIV. Claim 25, drawn in part to method of screening for agents that interact with one or more EOPIs s defined in claim 3, comprising contacting a population of cells expressing EOPI with a candidate agent and a control

agent, and comparing the level of mRNA encoding the EOPI in the first and second populations of cells, classified in class 435, subclass 6.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XV. Claim 25, drawn in part to method of screening for agents that interact with one or more EOPIs s defined in claim 3, comprising contacting a population of cells expressing EOPI with a candidate agent and a control agent, and comparing the level of induction of a downstream effector in the first and second population of cells, classified in class 435, subclass 7.32.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XVI. Claims 26-31, drawn in part to a method of screening for or identifying agents that modulate the expression or activity of one or more EOPIs as

defined in claim 3, comprising administering a candidate agent and a control agent to a mammal and comparing the level of expression of the EOPI protein, classified in class 435, subclass 4.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XVII. Claims 26-31, drawn in part to a method of screening for or identifying agents that modulate the expression or activity of one or more EOPIs as defined in claim 3, comprising administering a candidate agent and a control agent to a mammal and comparing the level of expression of the mRNA encoding the EOPI, classified in class 435, subclass 6.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XVIII. Claims 26-31, drawn in part to a method of screening for or identifying agents that modulate the expression or activity of one or more EOPIs as

defined in claim 3, comprising administering a candidate agent and control agent to a mammal and comparing the level of induction of a downstream effector, classified in class 435, subclass 4.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XIX. Claim 32, drawn to a method of screening for or identifying agent that modulate the activity of one or more of the EOPI as defined in claim 3, comprising contacting a candidate agent with EOPI, determining and comparing the activity of EOPI , classified in class 435, subclass 4.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XX. Claim 35-36, drawn to a method of screening for or diagnosis of ErbB2 related cancer in a subject, comprising contacting at least one

oligonucleotide probe and detecting and comparing the hybridization, classified in class 435, subclass 7.1.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XXI. Claim 37, drawn to a method of modulating the activity of one or more of the EOPI as defined in claim 3, comprising administering to a subject an agent identified by method of claim 23, classified in class 514, subclass 2.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XXII. Claim 38, drawn to a method of treating or preventing ErbB2 related cancer comprising administering an agent that modulates the activity of one or more of EOPIs as defined in claim 3, classified in class 424, subclass 130.1.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

XXIII. Claim 39, drawn to a method for identifying targets for therapeutic modulation of ErbB2 related cancer wherein the activity of one or more EOPI is utilized as a measure to determine whether a candidate target is effective for modulation of ErbB2-related cancer, classified in class 435, subclass 4.

If applicant elects this group for prosecution on the merits, applicant is required to further elect a single EOPI from Table 3. This election should not be construed as an election of species. This is a restriction requirement. Each of the EOPIs listed in Table 3 is a structurally and functionally distinct molecule (e.g. different PI, MW and sequence), which would require a separate search.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and VII-XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used

together. A method of screening or diagnosis of ErbB2 related cancer by using 2D electrophoresis and detecting EOFS (group I), a method of screening or diagnosis of ErbB2 related cancer by detecting EOPIs (group III), a method of treating ErbB2 related cancer (groups VII-XI, XXI and XXII), a method of screening for agents that modulate EOPIs (groups XII-XX), and a method for identifying targets for the therapeutic modulation of ErbB2 related cancer (group XXIII) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material and comprises different methodological steps. Moreover, the methodology and materials necessary for groups I, II, and VII-XXIII differ significantly for each of the materials. For group I, EOFs are detected and 2D electrophoresis is used, for group II, EOPIs are detected, for groups VII-XI, XXI and XXII, a agent is administered to a cancer patient to treat cancer, for groups XII-XX, a screening assay is used to identify a agent that can modulate EOPI, and for group XXIII, a target is identified for the therapeutic modulation of ErbB2 related cancer. Therefore, the methods of Groups I, II, VII-XI, XXI, XXII, XII-XX , and XXIII are patentably distinct. The inventions of Groups VII-XI, XXI, and XXII further differ from each other in that the material used to treat cancer in these methods is different. For group VII, an antibody that specifically binds EOPI is used, for group VIII, EOPI protein is used, for group IX, a nucleic acid encoding EOPI is used, for group X, an antisense molecule is used, for group XI, a robozyme is used, for group XXI, an agent that is identified by screening assay to be able to bind to EOPI is used, and for group XXI, an agent that modulates

the activity of EOPI is used. Moreover, inventions of groups XII-XX further differ from each other in that the assay used to screen for an agent that interacts or modulates EOPI is different. For group XII, the binding between the agent and EOPI is detected, for group XIII, a population of cells is used, and the level of EOPI protein is measured, for group XIV, a population of cells is used, and the level of EOPI nucleic acid is measured, for group XV, a population of cells is used, and the level of induction of a downstream effector is measured, for group XVI, an agent is administered to a mammal, and the level of EOPI protein is detected in the mammal, for group XII, an agent is administered to a mammal, and the level of EOPI nucleic acid is measured in the mammal, for group XVIII, an agent is administered to a mammal, and the level of the level of induction of a downstream effector is measured, for group XIX, the activity of EOPI is detected in the presence of the agent, and for group XX, a oligonucleotide probe is used and the hybridization is carried out. For these reasons, the inventions of Groups I, II, and VII-XXIII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search the inventions of I, II, and VII-XXIII together.

Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the EOPI can be used to generate antibodies as opposed to being used to treat cancer.

Searching the inventions of Groups III and VIII together would impose serious search burden. The inventions of Groups III and VIII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the EOPI and the methods of treating cancer using EOPI are not coextensive. The search for groups VIII would require a text search for the method steps. Prior art which teaches EOPI would not necessarily be applicable to the method of treating cancer using the EOPI. Moreover, even if the product was known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions IV and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cancer can be treated by the EOPI antibody as opposed to being treated by EOPI nucleic acid.

Searching the inventions of Groups IV and IX together would impose serious search burden. The inventions of Groups IV and IX have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the EOPI nucleic acid and the methods of treating cancer using EOPI nucleic acid are

not coextensive. The search for groups IX would require a text search for the method steps. Prior art which teaches EOPI nucleic acid would not necessarily be applicable to the method of treating cancer using the EOPI nucleic acid . Moreover, even if the product was known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cancer can be treated by the EOPI protein as opposed to being treated by EOPI antibody.

Searching the inventions of Groups V and VII together would impose serious search burden. The inventions of Groups V and VII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the EOPI antibody and the methods of treating cancer using EOPI antibody are not coextensive. The search for groups VII would require a text search for the method steps. Prior art which teaches EOPI antibody would not necessarily be applicable to the method of treating cancer using the EOPI antibody . Moreover, even if the product was known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Groups III-V are unrelated because they are drawn to structurally and functionally distinct molecules. The polypeptide of group III and the antibody of group V are patentably distinct for the following reasons: While the inventions of both group III and group V are polypeptides, in this instance the polypeptide of group III is a single chain molecule that functions as an enzyme, whereas the polypeptide of group V encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group III and the antibody of group V are structurally distinct molecules; any relationship between a polypeptide of group III and an antibody of group V is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. While the polypeptide of group III can be used to make antibodies of group V, the polypeptide of group III can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein. The polypeptide of group III and polynucleotide of group IV are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid

sequence of the encoded polypeptide. While a polypeptide of group III can be made using the polynucleotides of group IV, the polypeptide can also be made by another and materially different process, such as by peptide synthesis or purification from the natural source. Further, the polynucleotide may be used for the processes other than the production of the protein, such as nucleic acid hybridization. For these reasons, the inventions of groups III and IV are patentably distinct.

Furthermore, searching the inventions of groups III-V together would impose a serious search burden. In the instant case, the search of the polypeptides, antibodies and the polynucleotides are not coextensive. The inventions of groups III-V have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of groups I and II together.

Inventions III and any one of groups XII and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the EOPI can be used to generate antibodies as opposed to being used to identify a agent that modulates the activity of EOPI in a screening assay.

Searching the inventions of Groups III and any one of groups XII and XIX together would impose serious search burden. The inventions of Groups III and any one of groups of XII and XIX have a separate status in the art as shown by their

different classifications. Moreover, in the instant case, the search for the EOPI and the methods of screening an candidate agent using EOPI are not coextensive. The search for groups XII and XIX would require a text search for the method steps. Prior art which teaches EOPI would not necessarily be applicable to the method of screening an agent using the EOPI. Moreover, even if the product was known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Aug. 4, 2006